Conventional vs. Religious Cognitive Processing Therapy for Soldiers and U.S. Veterans with Post-Traumatic Stress Disorder

Having resilient and fit active duty soldiers who make up our armed forces and mentally healthy veterans who return from combat zones is critical to our success in preserving the freedom of our citizens and people throughout the world. In 2008, a RAND Corporation report estimated that nearly 20% of members of the U.S. armed forces (about 300,000 individuals) returning from Iraq and Afghanistan reported symptoms of post-traumatic stress disorder (PTSD) or major depression.\(^1\) PTSD is one of the most prevalent and disabling psychiatric disorders in military populations\(^2\) and is a major risk factor for suicide.\(^3\) PTSD is also the most common mental disorder among Iraq and Afghanistan veterans presenting for treatment at Veterans Affairs (VA) facilities.\(^4\) Only 20-30% of those with PTSD experience improvement that could be characterized as remission.\(^5\) Religious beliefs are important to many soldiers and veterans, often used to cope with the stress of war and trauma, and predict faster recovery in those with PTSD. In contrast, religious struggles and moral injury are associated with prolonged recovery and continued need for mental health services. A therapy that utilizes military personnel’s religious resources and addresses religious struggles and moral injury may be more effective than one that ignores them.

Duke University Medical Center, in collaboration with Eisenhower Army Medical Center (EAMC), Charlie Norwood VA Medical Center (CN-VAMC), and Womack Army Medical Center (WAMC), proposes a randomized clinical trial of CPT vs. RCPT for active duty soldiers and veterans with PTSD who have co-morbid combat-related physical injuries or illness and sleep problems. Soldiers/veterans will be enrolled if they (a) are at least somewhat religious, (b) have PTSD diagnosed with the SCID5 (subthreshold PTSD, PTSD without complications, PTSD with complications), (c) score 27 or higher on the PCL-5, (d) have at least one co-morbid physical injury/illness, and (e) have sleep problems. Participants will be randomized to twelve 50-min sessions over 6 wks of either standard Cognitive Processing Therapy (CPT) or religiously-integrated CPT (RCPT), and randomly assigned to master’s level counselors trained to deliver both treatments. Participants will be assessed blind to treatment group at baseline, 3, 6, 12, and 24-weeks using PCL-5, Pittsburgh Sleep Quality Index, Hospital Anxiety/Depression Scale, the ASSIST (substance abuse symptoms), and Moral Injury Scale, along with standard multi-item measures of religiosity, hope, purpose and meaning, optimism, self-esteem, post-traumatic growth, guilt & shame, and spiritual struggles. Christian, Jewish, Hindu, Buddhist, and Muslim versions of RCPT will be developed to match the soldiers’ or veteran’s faith tradition and preference. Six master’s level counselors, two at each site, will be trained to deliver both CPT and RCPT, to whom participants will be randomly assigned. Power analyses indicate that a sample size of 300 is needed to have 80% power to detect a small to moderate difference in treatment effect (d=0.38) at p=0.05 (2-tailed test) for the primary study aim.

A majority of psychotherapy clients (55% to 74%) have expressed a desire to discuss religious/spiritual issues during therapy,\(^6,7\) and we anticipate that this will be true for many soldiers and veterans frustrated that their symptoms are not responding to traditional treatments (only 20-30% of those with PTSD experience improvement that could be characterized as remission\(^8\)). If the efficacy of RCPT is established, the plan is
to train military chaplains on how to administer RCPT, both in the treatment and the prevention of PTSD. The significance of this research program is that it may help soldiers use their existing religious or spiritual resources to recover from (or avoid) psychological trauma from war and provide a transformative experience resulting in greater resilience while on active duty (for soldiers) and throughout the rest of their lives (soldiers & veterans).

**Background**

The lifetime prevalence of PTSD in the general community, according to the U.S. National Comorbidity Survey, is 7.8%. Rates of PTSD and associated comorbidities, however, are much higher among veteran and active military personnel. The lifetime prevalence of PTSD has been reported to be 15% in studies of Vietnam veterans, with one-month prevalence rates ranging from 2-15% and up to 36% in those exposed to high war zone stress. A recent meta-analysis of studies examining active military personnel (Canadian, US, and UK forces) following deployment to Iraq and Afghanistan reported that PTSD was highest in those involved in combat (10.9-13.4%) and those returning from Iraq (11.3-14.4%), compared to those deployed to Afghanistan (4.6-9.6%).

**PTSD Spectrum**

The target of this proposal is soldiers and U.S. veterans with subthreshold PTSD, uncomplicated classic PTSD, and complicated PTSD with co-morbid mental illness, all who also have co-occurring physical health problems. PTSD has long been known to exist on a spectrum from adjustment disorder (with significant sub-threshold PTSD symptoms), to standard uncomplicated PTSD, and to severe PTSD complicated with multiple co-morbidities. In a recent WHO report on structured psychiatric interviews conducted on 23,936 persons (non-military) in 13 countries experiencing some type of traumatic event, researchers found a prevalence of 3.0% for DSM-5 PTSD and 3.6% for those who met two or three of DSM-5 criteria B-E (subthreshold PTSD). Similar to those with standard PTSD, individuals with subthreshold PTSD had significantly elevated scores on distress-impairment, suicidality, comorbidity, and symptom duration. Studies in U.S. veterans likewise report high rates of subthreshold PTSD associated with significant mental and physical comorbidity. For example, in a random sample of 815 U.S. veterans seen in four VA primary care clinics in South Carolina evaluated with a DSM-IV structured psychiatric interview (CAPS), 12.5% met criteria for classic PTSD and an additional 4.0%-9.7% met subthreshold criteria depending on diagnostic method. When compared to those without PTSD, veterans with subthreshold PTSD had significantly greater PTSD symptom severity, poorer mental health overall, and poorer physical health (based on SF-36) (all p<0.001, regardless of how subthreshold PTSD was diagnosed).

**Psychiatric comorbidity**

PTSD also seldom exists as a pure disorder. The reality is that more than 80% of persons with PTSD lasting 3 months or longer have one or more co-morbid psychiatric disorders. The most common psychiatric disorders comorbid with PTSD are mood disorders, anxiety disorders, and substance abuse. The National Comorbidity Survey
found that even when PTSD was diagnosed in non-military community settings, the lifetime prevalence of comorbid major depression and dysthymia were 47.9% and 21.4%, respectively, and alcohol and drug abuse/dependence in 51.9% and 34.5%, respectively. Other studies have reported that major depression alone is present in 29.9% to 53.0% of those with PTSD.\textsuperscript{18,19}

Psychiatric comorbidity is even higher in veterans and active military with PTSD. One study of 2,490 Vietnam veterans found that among those with PTSD, 66% met criteria for a depressive or anxiety disorder and 39% for alcohol abuse or dependence.\textsuperscript{20} In a study of 3,016 Vietnam veterans, once considered the most comprehensive epidemiological study of veterans’ psychological adjustment, 98.9% of males with PTSD met criteria for another psychiatric disorder at some point in their lives.\textsuperscript{21}

Psychiatric comorbidity is especially high in veterans with both PTSD and physical health problems. Depression is not only widely prevalent but increases with time in medically ill veterans with PTSD.\textsuperscript{22} Likewise, substance abuse/dependence has been documented in 64% to 74% of veterans hospitalized for PTSD, and in up to 84% of those seeking outpatient treatment for PTSD.\textsuperscript{23}

When psychiatric comorbidity\textsuperscript{24} is combined with physical illness/injury,\textsuperscript{25} the risk of suicide among military personnel with PTSD increases dramatically,\textsuperscript{26} especially in those with TBI.\textsuperscript{27} Suicide rates in active duty US soldiers increased by over 50% from 10.3-11.3 per 100,000 in 2005 to 16.3 per 100,000 in 2008, and since 2009, suicide rates in the military have stabilized at approximately 18 per 100,000.\textsuperscript{28} Risk is especially higher in those with PTSD. Among soldiers who screen positive for PTSD using the PCL, the risk of completed suicide is nearly 80% higher than among soldiers who score below PCL cutoff scores.\textsuperscript{29} Cognitive therapies have been shown to reduce suicidal behaviors\textsuperscript{30} and may be an effective way to reduce suicide in active duty soldiers and veterans with PTSD.\textsuperscript{31}

Insomnia

Likewise, sleep problems are widely prevalent among soldiers/veterans, especially those with PTSD. One study found that 72% of active duty soldiers sleep less than 6 hours per night (considered “short sleep duration”)\textsuperscript{32} and nearly half of U.S. veterans meet criteria for insomnia.\textsuperscript{33,34} Insomnia is the most commonly reported symptom and predicts other symptoms of post-traumatic stress disorder in U.S. service members returning from military deployments.\textsuperscript{35} The same is true for veterans, and sleep problem are thought to be likewise related to PTSD.\textsuperscript{36} Research indicates that 70-91% of persons with PTSD have difficulty falling or staying asleep,\textsuperscript{37} including active duty soldiers\textsuperscript{38} and veterans\textsuperscript{39} (and have been shown to be effectively treated with cognitive-behavioral intervention).\textsuperscript{40}

Physical Comorbidity

In addition to co-morbid psychiatric disorders, as noted above, many soldiers and veterans will have traumatic war injuries or other health problems that cause physical disability. Burns, fractures, soft tissue injuries, and traumatic brain injury are the most common physical injuries that result from conventional warfare.\textsuperscript{41,42} When physical health problems are present the risk of PTSD is much higher, and in fact, increases over time. In a study of troops following return from deployment to Afghanistan or Iraq, rates
of PTSD ranged from 12.2% to 12.9%. In those with direct combat exposure and minor wounds or injury, however, the prevalence of PTSD was over three times higher.\textsuperscript{33} In a survey of 2,863 soldiers 1 year after deployment to Iraq, among those who were wounded or injured one or more times, 31.8% (150 of 471) met PTSD criteria, compared to only 13.6% (311 of 2,287) of those without injuries (OR=2.97, 95% CI=2.36–3.73).\textsuperscript{44} In another study of over 13,000 soldiers returning from deployment to Iraq, rates of PTSD and depression after returning from combat ranged from 9% to 31% depending on the level of physical disability reported.\textsuperscript{46} Chronic pain and cardiovascular disease are likewise common in active duty soldiers and veterans with PTSD.\textsuperscript{47,48}

**Moral Injury**

Since the 1980’s, war-time experiences such as violence, direct or indirect killing of enemy combatants and non-combatants (innocents), observing the death of fellow soldiers, and surviving when others have died, have been known to cause internal ethical conflict, guilt, and persistent distress.\textsuperscript{49} Only within the past 5-10 years, however, has the concept of “moral injury” received serious attention or been connected with PTSD, partly because of the resistance of PTSD to current treatments.\textsuperscript{50,51,52} Those with moral injury view themselves as immoral, irredeemable, and un-repairable, or believe that they live in an immoral world, making PTSD more difficult to treat unless this issue is addressed in therapy.\textsuperscript{53} Soldiers and veterans who are religious, have a religious background, or have been raised in a religious environment may be particularly vulnerable to moral conflict.\textsuperscript{54}

**Psychological Therapies for PTSD**

A recent review of psychological therapies for the treatment of PTSD found that the use of cognitive processing therapy (CPT) and prolonged exposure therapy (PE), which itself is based on CPT,\textsuperscript{55,56} are the primary evidence-based treatments used today.\textsuperscript{57} The effect sizes in clinical trials have generally been larger for these therapies than for those achieved by medication.\textsuperscript{58} CPT in particular has received increasing attention for the treatment of PTSD in soldiers and veterans.\textsuperscript{59,60,61,62,63,64,65,66} Both CPT and PE are manualized cognitive-behavioral interventions typically delivered in 12 sessions over 6-12 weeks.\textsuperscript{67,68} More than 2,300 VA clinicians have been trained in CPT and 1500 in PE, testifying to the effectiveness of these treatments.\textsuperscript{69,70} In fact, the VA has mandated that veterans with PTSD receive either CPT or PE.\textsuperscript{71} Unfortunately, these treatments seldom address the issue of moral injury and loss of faith, and despite the mandate, less than 10% of veterans with PTSD have completed a course in either CPT or PE.\textsuperscript{72,73,74}

**Religiously-Integrated Psychotherapy**

While there are many reasons why soldiers and veterans with PTSD are failing to complete CPT, one reason may be that those with strong religious beliefs might perceive these therapies as conflicting with their religious beliefs. Indeed, religious individuals often shy away from psychological therapies that are viewed as conflicting with their
beliefs systems. The long history of discord between religion and mental health care began nearly a century ago with Freud’s description of religion as “the universal obsessional neurosis.” A systematic review of the religious content of DSM-III-R found that nearly one-quarter of all cases of mental illness included religious descriptions. More recent publications by mental health professionals continue to reinforce the lack of concern for patients’ religious beliefs, and a recent national survey of U.S. psychiatrists found that 56% never, rarely, or only sometimes inquire about religious/spiritual issues in patients with depression or anxiety.

Based on this generally neglectful (and sometimes disparaging) attitude of many mental health professionals toward religion, religious professionals are often reluctant to refer members of their congregation to mental health professionals, especially for psychotherapy that seeks to alter religious beliefs and attitudes. Given that clergy represent a major first line treatment for depression in the community, the failure of clergy to refer may prevent many patients from receiving adequate treatment, including soldiers after discharge from the army. Furthermore, for military personnel who do participate in therapy and are members of a faith community, if their religious community does not support (or counteracts) the gains made in psychotherapy, then those gains may not last or treatment may be prematurely discontinued.

Thus, an evidence-based psychotherapy for PTSD that utilizes soldiers’ and veterans’ religious beliefs as part of the therapy may open the door for many military personnel with PTSD in need of treatment. A religious form of CPT that targets moral injury may be particularly effective, as religious struggles and even loss of faith are often present in those with combat-related PTSD. For example, in a collaborative effort between the VA National Center for PTSD and Yale University, researchers examined 1,385 veterans from Vietnam and WW-II or Korea to determine predictors of continued use of VA mental health services. Loss of religious faith as a result of killing others or failing to prevent the death of fellow soldiers was one factor measured. Interestingly, loss of faith was one of the most powerful predictors of VA mental health service use, more powerful than baseline severity of PTSD symptoms or deficits in social functioning. Researchers concluded that: “This possibility raises the broader issue of whether spirituality should be more central to the treatment of PTSD, either in the form of a greater role for pastoral counseling or of a wider inclusion of spiritual issues in traditional psychotherapy for PTSD” (p 579).

**Rationale for Addressing Religious Beliefs in Therapy**

Research indicates that greater religiosity predicts a faster resolution of depressive symptoms over time in those with physical illness (increasing speed of remission by 50 to 70 percent). This research includes medically ill U.S. veterans. Likewise, in a study of 600 veterans discharged from a substance abuse program, religious involvement predicted a 34% lower likelihood of being re-hospitalized during follow-up (RR=0.66, 95% CI 0.39-0.92). Furthermore, religious involvement (private religious activity and religious attendance) has been shown to distinguish resilient from non-resilient veterans in the National Health and Resilience in Veterans Study. Religious involvement did so by increasing emotional stability, serving as a protective psychosocial factor, and increasing social connectedness.
Veterans with PTSD serving in Iraq/Afghanistan have more religious struggles and lower self-rated religiosity compared to a matched sample of younger adults from the General Social Survey. The finding caused researchers to conclude that “the empirical and clinical information presented here highlights the need for expanded biopsychosocial-spiritual models of trauma that can account for both the adaptive role of religion/spirituality and address spiritual struggles in the recovery process.”

Studying a population of veterans returning from Iraq/Afghanistan, Ogden and colleagues likewise found that PTSD symptoms were significantly and positively associated with alienation from God, religious rifts, religious fear, and religious guilt. In contrast, post-traumatic growth (PTG) was significantly and positively associated with religious coping and prayer.

Studies reported within the past 12 months reinforce these findings. For example, religiosity/spirituality (R/S) has also recently been associated with PTG in a population-based survey of U.S. veterans. In that study, researchers in the Department of Veterans Affairs and in the Department of Psychiatry at Yale University analyzed data from the National Health and Resilience in Veterans Study that surveyed a nationally representative sample of 3,157 veterans in late 2011. The measures administered included a Trauma History Screen, the 17-item PTSD Checklist (PCL-S), and a 10-item Post-Traumatic Growth (PTG) Inventory-Short Form. In multivariate analyses that controlled for other risk factors, R/S was significantly and positively related to every aspect of PTG, including growth in intimate relationships (p<0.001), growth in new possibilities (p<0.001), growth in personal strength (p<0.001), spiritual growth (p<0.001), and growth in appreciation for life (p<0.001). In fact, of the 21 predictors that were examined, R/S was the second strongest predictor of overall PTG, and stronger than any psychological or social measure.

Military personnel with religious or spiritual resources have better outcomes than non-religious personnel in response to inpatient treatment programs for severe PTSD. For example, researchers from the National Center for PTSD at the Stanford University-Palo Alto VA examined baseline R/S as a predictor of PTSD outcomes in 532 veterans completing a 60-90 day residential treatment program for combat-related PTSD. R/S was assessed during the first week of the program and then again at discharge. PTSD severity was measured using the PCL-M at baseline and follow-up. Researchers were particularly interested in the cross-lagged effects (R/S predicting PTSD severity vs. PTSD severity predicting R/S) in order to determine “direct of effect.” Results indicated that baseline spirituality predicted significantly lower PTSD severity at discharge, independent of baseline PTSD severity. The cross-lagged effect of baseline R/S predicting discharge PTSD severity (p<0.05) was stronger than the cross-lagged effect of baseline PTSD severity predicting discharge R/S (p=ns), a finding that held up after controlling for confounders. R/S struggles, in contrast, were associated with worse PTSD outcomes, as many other studies have reported. R/S struggles could also serve as a target for a religiously-integrated CPT that focuses on strengthening spiritual and psychological resiliency.

Religious and Spiritual Therapies

Spiritual therapies have been effective in treating PTSD symptoms in military populations. For example, Bormann and colleagues examined the effectiveness of a
spiritual intervention (meditating using a sacred word/phrase) in reducing anxiety symptoms in veterans with PTSD. Subjects were randomly assigned to the spiritual intervention (n = 14) or delayed-treatment control (n = 15). Measures were PTSD symptoms, psychological distress, quality of life, and patient satisfaction. The spiritual intervention produced large effect sizes for reducing PTSD severity (d = −.72), psychological distress (d = −.73), and increasing quality of life (d = .70). Mindfulness meditation, a Buddhist form of contemplative prayer, has also received increasing attention as a treatment for PTSD.

In related research, religiously-integrated CBT has been shown to increase the speed of remission in depressed religious patients above and beyond that achieved by conventional CBT. Likewise, a number of studies that have utilized patients’ religious beliefs in psychotherapy have reported results superior to secular treatments or usual care, especially in religious patients. Religiously-integrated CBT has been shown to effectively treat major depression in persons with chronic medical illness, especially in more religious clients. A religious form of psychotherapy for the treatment of soldiers and veterans with PTSD, however, has yet to be developed or tested.

Will Soldiers and Veterans Be Receptive?

Religious involvement is important to many in the general U.S. population, from which soldiers and veterans are drawn. A January 2009 Gallup Poll reported that 65% of Americans said that religion is an important part of their daily life, a figure which increased to over 75% in the southeastern U.S. (where the present study is planned). This is especially true for people with physical disability, who often turn to religious beliefs to cope with health problems. In some areas of the U.S., nearly 90% of persons with physical illness use religion to cope and of those, nearly half (45%) report that religion is the most important factor that keeps them going. High rates of religious coping have likewise been documented in veterans with physical illness. Although not yet studied in military populations, research indicates that 55% to 74% of psychotherapy clients express a desire to discuss religious/spiritual issues during therapy.

What do we know about the religious interests of active duty soldiers? In 2011 a survey of 34,416 military personnel in the Department of Defense (i.e., Army, Navy, Marine Corps, Air Force) and 5,461 personnel in the Coast Guard found that nearly two-thirds (63.6%) classified themselves as medium (35.3%) or high (28.3%) on religiosity/spirituality (R/S), whereas 14.0% indicate low and 22.4% indicated not applicable. Soldiers reporting high R/S experienced less heavy alcohol use (4.8% vs. 8.4%), less cigarette smoking (15.9% vs. 24.0%), less drinking and driving (4.0%), and less negative affect (6.7% vs. 9.6%) compared to those reporting lower levels of R/S. According to the most recent survey in 2013, 74% of active duty Army personnel (n=528,070) indicated a religious affiliation, and in an additional 8%, religious affiliation was unknown (some of whom may also have been religiously affiliated). Of those with a religious affiliation, 97% were Christian (53.1% Protestant, 18.9% Catholic, 0.1% Orthodox). Only 0.6% described themselves as atheist.

Bear in mind that these figures are for active duty soldiers in general, and are not specific to soldiers returning from war zones or injured during combat. Because religion is often used to cope with distress, religious involvement may be even higher in military personnel with PTSD, as research has suggested. Furthermore, consistent with
culturally competent therapy, a religiously-integrated CPT may be particularly attractive to and appreciated by soldiers and veterans from minority populations (Blacks, Hispanics, etc.) who tend to be much more religious than Caucasians, a pattern that is also seen in the general population.\textsuperscript{121,122} For many active duty soldiers and U.S. veterans, then, we estimate that receptivity will be high to a religiously-integrated form of psychotherapy for PTSD. This would be particularly true if religiously-integrated CPT addressed religion/spirituality as both a coping resource and a potential source of moral conflict and pain (i.e., spiritual struggles).

Summary

PTSD and its associated mental comorbidities, particularly insomnia, and physical health problems (1) are widespread among U.S. soldiers and veterans who have been deployed to combat zones, (2) cause tremendous emotional and physical disability, and (3) may be influenced both in their development and course by religious involvement. War time experiences can also affect soldiers’ and veterans’ religious beliefs and cause moral injury and religious struggles, reducing resiliency and adversely affect ability to cope with stress and deal with sleep problems.\textsuperscript{123,124} While a recent review of psychological therapies for PTSD in the military indicated that “the vast majority of articles focus on cognitive-behavioral approaches to treatment, and this area of the literature present strong evidence for these approaches,” researchers acknowledged that further randomized clinical trials are necessary since PTSD is often a challenging and treatment-resistant condition.\textsuperscript{125} Religious beliefs are prevalent among soldiers and veterans, and these are often used to cope with stressors related to war-time experiences, injuries and disabling health problems. Moreover, religious beliefs and involvement has been associated with faster recovery from PTSD in observational studies.\textsuperscript{126,127} A psychological therapy that takes advantage of soldiers’ and veterans’ religious resources and addresses spiritual struggles and moral injuries, then, has the potential to improve PTSD and its associated comorbidities more quickly than one that ignores them. The goal of religiously-integrated CPT is to heal and increase the resiliency of military personnel with PTSD and co-morbid conditions, and counter the high rate of suicide associated with this disorder. Resilient soldiers will make better soldiers, and resilient veterans will be more productive citizens and family members.

Specific Aims

Specific Aim #1. Determine if RCPT is more effective than CPT in the treatment of soldiers and veterans with PTSD and physical health problems.

Hypothesis #1.1: RCPT will be more effective than CPT in reducing severity of PTSD symptoms by the end of treatment (6 weeks from baseline).

Hypothesis #1.2: The superiority of RCPT over CPT will persist for at least 18 weeks after treatment has ended (24 weeks from baseline).

Specific Aim #2. Examine the effectiveness of RCPT vs. CPT on co-morbid mental disorders and sleep problems.

Hypothesis #2: RCPT will be more effective than CPT in decreasing depressive symptoms, anxiety symptoms, substance use, and sleep problems; differences in
treatment effects will be present by 6 weeks from baseline (at the completion of therapy) and will persist for at least 18 weeks afterwards (24 weeks).

Specific Aim #3. Identify psychological and social mechanisms by which RCPT has its effects.
Hypothesis #3: RCPT will be more effective than CPT in increasing hope, purpose and meaning in life, optimism, self-esteem, and post-traumatic growth, increasing social support, and reducing shame, guilt, and negative religious coping, which will mediate and at least partially explain the superiority of RCPT over CPT in relieving PTSD symptoms.

Specific Aim #4. Examine the effectiveness of RCPT vs. CPT on moral injury, a known factor that may lead to treatment resistance.
Hypothesis #4: RCPT will be more effective than CPT in reducing moral injury; differences in treatment effects will be present by 6 weeks from baseline (at the completion of therapy) and will persist for at least 18 weeks afterwards (24 weeks).

Specific Aim #5. Religiosity will moderate the effect of RCPT on PTSD symptom severity, co-morbid mental disorders, and sleep problems.
Hypothesis #5: RCPT will be especially effective in those who are more religious at baseline (i.e., score ½ standard deviation or more above the mean on our multi-dimensional religiosity scale). This moderating effect of religiosity will be observed at 6 weeks from baseline (at the completion of therapy) and will persist for at least 18 weeks afterwards (24 weeks).

METHODS

We propose a head-to-head randomized clinical trial involving 300 eligible soldiers and veterans recruited from two army medical centers and a VA medical center (including both outpatient and inpatients). A total of 100 active duty army soldiers will be recruited from EAMC, 100 from WAMC, and 100 veterans from CN-VAMC.

Inclusion/Exclusion Criteria

Inclusion criteria are (1) a diagnosis of PTSD or subthreshold PTSD on the SCID-5; (2) a score of 27 or higher on the PCL-5 (equivalent to 40 or higher on PCL-S); (3) any comorbid physical illness resulting from combat injury or other medical illness lasting at least one month or longer; (4) problems falling or staying asleep; (5) religion is self-rated as at least somewhat important; (6) English-speaking; and (7) willingness to provide written informed consent, and complete follow-up interviews. Exclusion criteria are (1) cognitive dysfunction as indicated by a score of 13 or lower on the 18-item abbreviated Mini-Mental State Exam; (2) receipt of CPT within the past 4 weeks; and (3) active suicidal ideation with significant risk. Participants will be allowed to have other co-morbid psychiatric disorders (depressive disorder, bipolar disorder, anxiety disorder, substance abuse) that will be documented at baseline using the SCID-5. Participants will be allowed to take medication for psychiatric symptoms, including antidepressants (SSRIs) as recommended by the DOD-VA Clinical Practice Guidelines, although the regimen should be stable or unchanged within the past month.
Feasibility

**Eisenhower Army Medical Center.** Clinicians at this facility see 10 new and 40-50 ongoing cases of PTSD per month (75% with comorbid psychiatric or medical disorders). During a 24-month recruitment period, this means that 240 new cases of PTSD and over 1,000 soldiers being followed for PTSD will come through the doors. If 50% have co-morbid physical problems, there will be over 600 soldiers from which 100 participants will need to be enrolled.

This does not include the large number of soldiers with PTSD symptoms at Fort Gordon returning from deployment to war zones who are not currently being treated but who may be eligible to participate in this study and could be identified by advertising, word of mouth, or screening. Note that in a recent study (November 2013) of 1,707 soldiers of an infantry brigade that participated in the Walter Reed Army Institute of Research Land Combat Study, 16% scored 28 or higher on the PCL-5 and among the 937 returning from Iraq or Afghanistan, 24% scored 27 or higher. Surveys indicate that only about 23% to 40% of soldiers with PTSD and other disorders seek help for their symptoms, meaning that many soldiers at Fort Gordon with significant symptoms may not be receiving treatment.

**Womack Army Medical Center.** Clinicians see 40 new and 200 ongoing cases of PTSD per month, four times the number seen at EAMC. During a 24-month period, then, close to 1000 soldiers with new PTSD will be assessed and at least 2,000 with ongoing PTSD will be followed. Again, this number does not include soldiers with subthreshold PTSD or those with PTSD who have not sought help for their symptoms (identified by screening or advertisements) who would be eligible for the study.

**Charlie Norwood VA Medical Center.** Clinicians at CN-VAMC see 90 new veterans with PTSD per month and follow 150-200 veterans with PTSD. Therefore, during a 24-month recruitment period, clinicians will see 2,160 new cases of PTSD and follow up at least 1,500-2,000 veterans with PTSD. Again, if 50% have co-morbid physical health problems, there will be over 2,000 veterans from which 101 veterans will need to be enrolled. If there are problems meeting the recruitment goal at the other sites, we believe that at least 150 veterans could be enrolled from the CN-VAMC site.

As with EAMC and WAMC, there may also be many veterans receiving treatment at CN-VAMC for other psychiatric disorders or for medical problems, veterans who have PTSD symptoms but have not received treatment for these symptoms and so may be eligible to participate in this study (and, as at Fort Gordon, could be identified by advertising, word of mouth, or screening). In one survey of over 103,000 veterans from Iraq or Afghanistan receiving VA outpatient services, 13% had a diagnosis of PTSD documented in their medical records (not counting those who were not assessed for PTSD). An additional 4-10% of veterans are likely to have subthreshold PTSD that is associated with considerable mental and physical co-morbidity.

In conclusion, there should be adequate numbers of soldiers and veterans with PTSD or subthreshold PTSD at the three sites above who could be enrolled into the study to meet recruitment goals.
Procedure
Potential participants will be screened in-person or by telephone to determine if they meet the initial eligibility criteria based on inclusion/exclusion criteria. This initial screening can quickly determine the presence of (a) a prior diagnosis of PTSD or PTSD-like symptoms resulting from war-time experiences or sexual assault, (b) one or more comorbid physical health problems, (c) if participant is at least somewhat religious, (d) willing to participate in study and go through the follow-up assessments, and (e) absence of CPT in the past 4 weeks. At EAMC and WAMC, research coordinators (RC) may invoke/use a partial HIPPA waiver, which will enable them to go through the medical records to identify soldiers who are potentially eligible for the study, and then cold-call them (without separate approval from treating clinicians). This may also be possible at the Augusta VAMC. In addition, flyers for the study will be posted, posters developed, and staffers/chaplains encouraged to identify potential participants and direct them to the RC.

After screening the participant by telephone, a visit will be arranged when in-person informed consent will be obtained and further screening conducted to ensure that all inclusion/exclusion criteria are met. Participants who meet eligibility criteria will then complete a baseline evaluation, be provided with a description of the two treatment options (CPT and RCPT), be asked to choose their preferred religion (should they be randomized to the RCBT condition), and then randomized to RCPT or CPT. A separate Clinical Trials Control Center (CTCC) will randomize participants to treatment group using a 4-person block design to ensure similar numbers in each group, as well as randomize them to therapist. The assignment will be provided by the RC to the participant in a sealed envelope that contains the treatment arm and therapist to which the participant is assigned. This assures that the RCs (interviewers) remain blind to treatment group. The CTCC will then connect participants with their therapists for an initial meeting, and will schedule and track treatment sessions and follow-up assessments at 3 weeks, 6 weeks, 12 weeks and 24 weeks from baseline. We will obtain approval from the Institutional Review Boards at DUMC, EAMC, WAMC, and CN-VAMC to conduct the study.

Interventions
Conventional CPT. CPT is an established and proven treatment for PTSD, and is recommended as one of the primary evidence-based trauma-focused psychotherapies for PTSD according to the DOD-VA Clinical Practice Guidelines. CPT differs from PE in that the former is more heavily based in the social cognitive theory of PTSD, which emphasizes how certain emotional responses (e.g., shame, guilt, anger, humiliation) result from erroneous interpretations of the trauma. CPT will be carried out by therapists guided by the standard CPT manual, with workbooks for therapist and patient.

More specifically, when an individual has faced a traumatic event, he/she will cognitively try to reconcile the information about the event with previous schemas. As a result, he/she will go through one of three cognitive processes: 1) assimilation, i.e., alter the incoming information to match prior beliefs; 2) accommodation, i.e., alter beliefs enough to incorporate the new information; and 3) over-accommodation, i.e., alter beliefs about oneself and world to an extreme degree in order to feel safer and in more control. CCPT helps the individual accommodate or alter beliefs associated with the trauma to
incorporate new information and allow the individual to be able to fully process the trauma affectively. During the process of accommodation, as beliefs associated with the trauma are challenged, it is expected that secondary emotions and intrusive reminders will dissolve.

The main aspects of CCPT include (a) educating the individual about PTSD and the efficacy of treatment; (b) helping him/her to become aware of the connection between cognitions and emotions associated with the trauma; (c) utilizing cognitive restructuring and Socratic questioning to challenge maladaptive thinking patterns, particularly those related to blame and guilt; and (d) addressing topics such as safety, trust, power/control, esteem, and intimacy that may have been disrupted as a result of the trauma.\(^{135}\)

**Religiously-integrated CPT.** The CPT manual used for the CPT group will be adapted to create a religiously-integrated form of CPT. This procedure will follow that used in our previous work developing religiously-integrated CBT (cognitive behavioral therapy).\(^{136}\) The latter has been shown to effectively treat clients with major depressive disorder in the setting of chronic health problems, especially in clients who are more religious.\(^{137}\) As with our RCBT intervention, RCPT will be manual-based and workbooks for therapist and patient will be developed for Christian, Jewish, Muslim, Buddhist, and Hindu faith traditions.

RCPT targets erroneous interpretations of trauma by focusing on cognitive restructuring using clients’ religious resources (i.e., religious beliefs, practices, scriptures, values, and motivations) to challenge maladaptive thinking patterns. Religious concepts of mercy, grace, repentance, forgiveness, spiritual surrender, prayer/contemplation, divine justice, hope, and divine affirmations are discussed as means to reverse negative emotional responses, such as shame, guilt, anger, and humiliation. These are supplemented by powerful religious confession and forgiveness rituals, song, and emersion within a faith community. Moral injury and spiritual struggles are specifically addressed. Many great religious figures engaged in battle and killed – including Abraham, Moses, Joshua, David (author of the Psalms), the Prophet Mohammed, and Lord Krishnan. These individuals are presented as role models that soldiers/veterans may identify with.

Prior to randomization, participants will have the five types of RCPT explained to them and they will choose which type they wish to receive should they be randomized to the RCPT arm. Our religious CBT intervention has been standardized, field-tested, and is available on the Duke University website (therapy manuals, therapist workbook, and client workbook for the conventional CBT and for each of the five religiously-integrated CBT treatments).\(^{138}\) Numerous publications from our recent multi-center trial using these interventions are either in print, in press, or in submission.\(^{139,140,141,142,143,144,145,146,147,148,149,150}\)

**CPT and RCPT Session Outline**

(Christian version here; to be adapted for Jews, Muslims, Buddhists, Hindus)

**CCPT Session 1:** Focuses on rapport building, education on PTSD symptomatology, providing the rationale for cognitive processing treatment of PTSD, explaining the course of treatment, and eliciting treatment compliance. During this session, the therapist and patient define the most traumatic event to be targeted first in treatment. For homework,
patients write a trauma statement describing the impact the trauma has had on their beliefs about self, others, and the world.

**RCPT Session 1:** Focuses on rapport building, education on PTSD, depression, and moral injury as a major cause/maintaining factor of PTSD (i.e., shame and guilt for not acting in accord with their morals, values, and religious beliefs), the rationale for Christian based cognitive processing treatment of PTSD (can use language such as, Christ as our Commander in Chief, spiritual armor rather than physical armor, part of a new, eternal army/family of God to provide the closeness/intimacy/brotherhood they had in the military and have now lost), explaining the course of treatment, and eliciting treatment compliance. During the session, the therapist and patient define the most traumatic event to be targeted first in treatment. For homework, patients write a trauma statement describing the impact the trauma has had on their beliefs about God, self, others, the world, and their religious beliefs and practices and spiritual well-being. Patients are given verse to inspire/set intention of hope (Ecclesiastes 1:1-11).

**CCPT Session 2:** Targets the meaning of the traumatic event. Patients are encouraged to read the impact statement in session to elicit an affective response and reduce trauma-related avoidance. The meaning of the impact statement is discussed. The patient is further socialized to the CPT model by reviewing symptoms of PTSD and the theory of PTSD treatment. The relationship between thoughts, feelings, and behavior, particularly as they relate to the trauma, are introduced using the A-B-C worksheet. For homework, patients complete an A-B-C worksheet daily to help identify connections between thoughts, emotions, behavior, and trauma.

**RCPT Session 2:** Targets the meaning of the traumatic event, particularly as it relates to moral injury and changes in their religious beliefs and practices. Patients are encouraged to read the impact statement in session to elicit an affective response and reduce trauma-related avoidance. The meaning of the impact statement is discussed and examples of how symptoms of PTSD, moral injury, and spiritual struggles are exemplified in Biblical stories. The relationship between thoughts, feelings, and behavior, particularly as they relate to the trauma, are introduced using the A-B-C worksheet. Biblical example of David and Bathsheba used for A-B-C example (war example; God as both just and merciful; consequences for our actions, but also complete forgiveness and right-standing before God). For homework, patients meditate on a scripture related to the session material (David’s plea for forgiveness in Psalms) and complete an A-B-C worksheet daily to help identify connections between thoughts, emotions, behavior, and trauma.

**CCPT Session 3:** Begins with review of the A-B-C worksheets completed for homework. The therapist identifies emotional and/or cognitive themes from the worksheets and helps patients revise any misidentified cognitions and emotions. Stuck points, the concepts of assimilation versus (over) accommodation, self-blame, and guilt are discussed and gently challenged through Socratic questioning. For homework, patients write a detailed account of the trauma to include sensory details (sights, sounds, and smells, etc.) as well as additional thoughts and emotions that are recalled about the traumatic event. Patients also continue to complete A-B-C worksheets.

**RCPT Session 3:** Begins with a review of the A-B-C worksheets completed for homework. The therapist identifies emotional and/or cognitive themes from the
worksheets and helps patients revise any misidentified cognitions and emotions. Stuck points are discussed, particularly as they relate to moral injury, self-blame, and spiritual struggles. The concepts of repentance and confession are introduced as healing religious resources. For homework, patients will write a detailed account of the trauma/moral injury to include sensory details (sights, sounds, smells, etc.), as well as additional thoughts and emotions that are recalled about the traumatic event/moral injury. They will then read this statement and confess the moral injury/wrongdoing aloud daily. Patients will be provided another scripture to meditate on (verse on confession) and will continue to complete A-B-C worksheets.

CCPT Session 4: Begins with the reading of the trauma account. As patients read the account, the therapist helps to identify thoughts and feelings associated with the traumatic event. This exercise allows patients to engage in affective expression and both the therapist and patient to identify stuck/missing points in the narrative. For homework, patients rewrite the trauma account, providing more sensory details, thoughts, and feelings experienced during the incident. Patients then read the trauma account every day until the next session, as well as continue to complete the A-B-C worksheets.

RCPT Session 4: Begins with the reading of the trauma/moral injury account and confession. As patients read the account, the therapist helps to identify thoughts and feelings associated with the moral injury and traumatic event. This exercise allows patients to engage in affective expression and both the therapist and patient to identify stuck/missing points in the narrative. The therapist listens for ways patients’ religious faith may be serving as a resource and/or a source of struggle. The concepts of grace, mercy, divine love, and divine justice are introduced (use story of Prodigal son—father waiting, running out to meet him; we are fully known by God and fully loved—the ultimate desire of our hearts). For homework, patients rewrite the trauma account/moral injury confession, providing more sensory details, thoughts, and feelings experienced during the incident. Patients then confess the moral injury out loud daily and meditate on relevant scriptures daily (verse on mercy/grace), as well as continue to complete A-B-C worksheets.

CCPT Session 5: Begins with reviewing the newest version of the trauma account. Patients are asked to identify similarities and differences between how they felt during the incident and while writing the account. Further, patients are asked to delineate differences between the first and second trauma account. The expectation is a lessening of emotional intensity with the second account if they are allowed affective expression to occur in the first account. The Challenging Questions worksheet is introduced, a tool to assist patients in challenging their maladaptive trauma-related beliefs and stuck points, particularly those associated with self-blame. For homework, patients use the Challenging Questions and A-B-C worksheets to challenge one maladaptive belief daily. If necessary, patients will also complete unfinished written trauma accounts.

RCPT Session 5: Begins by reviewing the newest version of the trauma account/moral injury confession. Patients are asked to delineate differences between the first and second trauma account/moral injury confession. Forgiveness and penance (praying for those they hurt or their enemies; verbally blessing them) are introduced as ways to deal with moral injury and self-blame. For homework, patients pray prayers requesting,
granting, and receiving forgiveness (or asking for the desire/willingness to forgive if they are not ready to do so. They will also pray and say statements of blessing daily for the people they wronged and for their enemies Patients will be encouraged to meditate on a relevant scripture passage (verse on forgiveness).

**CCPT Session 6:** Begins with reviewing the challenging questions worksheets and assisting patients in examining and working through their maladaptive beliefs. Patients begin to take on more of an active role in therapy while the therapist takes on a more supportive and consultative role. The Patterns of Problematic Thinking worksheet is introduced, a tool to assist patients in identifying counterproductive thinking patterns instead of a single thought. For homework, patients identify problematic thinking patterns related to the traumatic event and how their reactions to the event may have been affected by the problematic thinking patterns. If patients continue to experience intense emotions associated with the trauma, then daily reading of the trauma account should continue.

**RCPT Session 6:** Begins with reviewing the forgiveness and penance exercise. The Patterns of Problematic Thinking worksheet, with theological reflections for each pattern of thinking, is introduced, a tool to assist patients in identifying counterproductive thinking patterns instead of a single thought. Communion/The Eucharist is discussed as a ritual for purification. For homework, patients identify problematic thinking patterns related to the traumatic event, how their reactions may have been affected by the problematic thinking patterns, and how their religious teachings (theological reflection) help to challenge this type of thinking. Patients will also be asked to participate in Communion/The Eucharist, pray and bless those they hurt (now referred to as penance), meditate on a relevant scripture passage (verse on renewing the mind). They will also be encouraged to continue the steps toward forgiveness, if there are others they need to forgive or things they need to be forgiven for.

**CCPT Session 7:** Begins with reviewing the Patterns of Problematic Thinking worksheet. Patients then learn how to replace automatic maladaptive cognitions with more adaptive beliefs. The Challenging Beliefs worksheet is introduced on which patients rate the strength of the emotion and the problematic thinking pattern associated with the maladaptive thought. The Challenging Questions and Patterns of Problematic Thinking worksheets are then used to generate a more balanced and evidenced based statement. Finally, the topic of safety is discussed. Specifically, how previous beliefs regarding safety might have been disrupted or seemingly confirmed by the traumatic event. For homework, patients read the safety module in the patient workbook and complete at least one Challenging Beliefs worksheet on a maladaptive belief associated with safety related to self and others. If safety is not an issue for patients, then they will be encouraged to complete worksheets on other maladaptive beliefs and recent- distressing trauma related events.

**RCPT Session 7:** Begins with reviewing the Problematic Thinking worksheet. Patients then learn how to replace automatic maladaptive cognitions with more adaptive beliefs using their religious resources. The Challenging Beliefs and Challenging Questions worksheet will be introduced on which participants rate the strength of the emotion and the problematic thinking pattern associated with the maladaptive thought. The Challenging Questions and Patterns of Problematic Thinking worksheets, along with
religious resources (e.g., scriptures, religious teachings, religious practices), are then used to generate a more balanced and evidenced based statement. Finally, the topics of spiritual grief, trusting in God, and feeling betrayed or abandoned by God are discussed. Specifically, how these struggles and beliefs undermine their ability to trust and feel secure. For homework, patients read the module on Divine love and meditate on scriptures about the unconditional love and unchanging nature of God. Patients complete at least one Challenging Beliefs worksheet on a maladaptive belief associated with spiritual struggles, trust, and/or security. They will continue to engage in penance and confess verses on forgiveness.

**CCPT Session 8:** Begins with review of Safety or Challenging Beliefs worksheets. The therapist helps patients to challenge problematic beliefs that they were unable to successfully complete on their own. The topic of trust is introduced and the module on trust in the patient workbook is reviewed. For homework, patients complete at least one worksheet that confronts maladaptive cognitions associated with trust related to self or other, if this is an area of concern. Otherwise, patients will continue to complete worksheets on safety or will challenge other trauma-related maladaptive beliefs.

**RCPT Session 8:** Begins with review of the Divine love module and Challenging Beliefs worksheets. The therapist helps patients to challenge problematic beliefs that they were unable to successfully complete on their own. The topic of healing (emotional, physical, and spiritual) and scriptures associated with healing (e.g., story of Jesus by healing pool when he asks the paralyzed man “Will you be made well?”) are introduced and the module on healing in the patient workbook is reviewed. A discussion on how God is not bound by time or space and as such healing for traumatic memories is possible. Patients are led through a guided imagery/prayer on finding God/Christ in the traumatic memory. For homework, patients mentally revisit the revised memory daily, engage in penance, and confess verses on healing.

**CCPT Session 9:** Begins with a review of the homework exercises. The theme of the session is power and control and how these schemas have been affected (confirmed or disrupted) by the trauma. For homework, patients read the power/control module in the patient workbook and complete the worksheets on this topic related to self and others, as well as on safety and/or trust if necessary. The challenging beliefs worksheets can also be used to address ongoing maladaptive beliefs.

**RCPT Session 9:** Begins with a review of the homework. The theme of the session is power and control and how these schemas have been affected (confirmed or disrupted) by the trauma and moral injury. The concepts of God’s sovereignty and a discrepancy between God’s character and one’s lived experience are introduced. Also discussed are the limits to one’s moral agency, power, and responsibility. Active surrender is introduced as a tool that can be used to help resolve or accept potential discrepancies and inflated or distorted beliefs in this area. Scriptures on power/control are also shared with patients (verse on only God being God). For homework, patients read the power/control module in the patient workbook and complete worksheets on this topic related to God, self, and others. They will also continue to engage in penance and confess verses on God’s power and control/surrendering to God.
**CCPT Session 10:** Begins with a review of the *Power/Control* worksheets. The topic of esteem (self-esteem and regard for others) is introduced, followed by a discussion on how esteem can be disrupted by traumatic events. For homework, patients read the esteem module and complete worksheets on this topic related to self and others. Patients are also asked to practice giving and receiving compliments during the week and doing at least one nice thing for themselves each day.

**RCPT Session 10:** Begins with a review of the *Power/Control* worksheets. The topic of self-empathy and other-focused empathy inspired by God’s love is introduced, followed by a discussion on how empathy can be disrupted by traumatic events. Post traumatic growth, including spiritual growth, is introduced from a religious perspective. Biblical examples of people who grew through trauma and challenges are provided and discussed. For homework, patients read the empathy module and complete worksheets on this topic related to God, self, and others. Patients are given scriptures based on God’s love and affirmations to meditate upon. They will also be asked to practice giving and receiving compliments during the week and identifying at least one positive way they have grown through this experience. They will also continue to engage in penance.

**CCPT Session 11:** Begins with a review of the homework. The topic of intimacy is introduced and how relationships may have been impacted by the traumatic incident is discussed. For homework, patients complete worksheets on intimacy related to self and others, and continue to work on stuck points from previous topics that remain problematic. Finally, patients are asked to rewrite the impact statement from session one.

**RCPT Session 11:** Begins with a review of the homework. The topic of intimacy is introduced and discussed is how relationships, including a relationship with God, may have been impacted by the traumatic incident. The account of Judas and Peter’s moral injury and subsequent actions will be contrasted. Also discussed are ways to move toward God and others in the patients’ religious community (e.g., through altruism, compassion, prayer, social support). For homework, patients complete worksheets on intimacy related to God, self, and others. Patients will also be provided scriptures related to intimacy to meditate upon, will engage in penance, and will take one step toward greater intimacy with someone in their religious community. Finally, patients are asked to write a statement in which they look for positive growth and how they intend to live going forward transformed rather than deformed by the moral injury and God’s healing power.

**CCPT Session 12:** Begins by reviewing the homework. Patients are asked to read the new impact statement and then compare it to the original impact statement. Changes and growth are discussed. The rest of the session is spent reviewing the course of treatment, identifying any remaining issues that need further attention, and setting future goals.

**RCPT Session 12:** Begins by reviewing the homework. Patients are asked to read the new impact statement and compare it to the original impact statement. Changes and growth are discussed, particularly as they relate to trauma/moral injury and spiritual well-being. Patients are encouraged to create a “Clean Monday,” which is the day after Lent in which people fly kites to celebrate the resurrection and new life. The rest of the session is spent reviewing the course of treatment, identifying any remaining issues that need further attention, discussing hope, and setting future goals.
Interfaith Panel

Faculty psychotherapists (PhD or MD) experienced with cognitive therapy and with integrating religious beliefs into therapy from Christian, Jewish, Muslim, Buddhist, and Hindu perspectives will form an interfaith panel. They will assist in the development of the four non-Christian versions of the religiously-integrated CPT manual and workbooks, and will help to supervise therapists if a subject from their faith tradition is enrolled into the study.

Therapists

Licensed counselors (at the master’s degree level) will administer twelve 50 min sessions of CPT in-person over 6 weeks.\(^1\) We have compressed the sessions which are usually provided over 12 weeks to 6 weeks, since our previous clinical trial found that most improvement occurs within the first 4 weeks of treatment.\(^{151}\) Six community-based counselors will be hired from outside the military by Duke to administer the interventions (two therapists for each site). CPT and RCPT therapists will be trained onsite for the trial and supervised by telephone throughout the trial by Duke Faculty skilled in CPT (O’Garo) and religious CBT (Pearce).

To qualify as a study therapist, a score of 40 or higher based on ratings by supervising faculty on recordings of therapy delivered will be required on the Cognitive Therapy Rating Scale (CTRS), a measure of therapy competence that we will adapt for CPT.\(^ {152,153}\) Treatment adherence will be assessed using an adapted version of the Adherence Rating Scale (ARS), which assesses adherence to session structure (range 0-15), development of the therapeutic relationship (range 0-6), adherence to the manual (range 0-8), therapist competence (range 1-4), and flexibility (range 1-4).\(^ {154}\) A 10% random sample of sessions will be tape recorded (n=300), of which 50% will be randomly selected (n=150 or 25 per therapist), transcribed, and rated by trained and supervised raters otherwise not directly involved in the study. The tape recorded sessions will be weighted towards the beginning of the study so that corrective actions may be taken early on if there are problems with adherence.

Therapists will be paid $75 for each 50-minute session completed and receive a flat fee of $1,000 at the end of the study for time spent during training and supervision sessions.

Treatment Attrition

Dropout rates prior to completing the full course of religiously-integrated therapies (and control therapies) have been reported to range from less than 10% to up to 40%.\(^ {155,156}\) We are projecting a dropout rate of 25% for the present study, which is reasonable given this military population with multiple comorbidities including substance abuse.

MEASURES

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\(^1\) At first thought to include PhD/PsyD as therapists. However, think it might be better to use master’s level counselors for the clinical trial to determine treatment efficacy (RCPT superior over CCPT). However, the ultimate plan is to train master’s level military chaplains and VA chaplains to administer religiously-integrated CPT in their respective settings, given their background, expertise, and responsibility in addressing moral injury and religious struggles. Currently, chaplains do not provide CPT.
Demographic Factors

Demographics assessed will be age, gender, race/ethnicity, education, marital status, living situation, and number of children. Information about current and past military service will also be collected, including branch of service, time in the military, current status (active duty vs. retired veteran), type and length of previous deployments, time since last deployment, and time since primary traumatic experience (Criterion A).

PTSD Diagnosis and Severity

PTSD Diagnosis. The diagnosis of PTSD will be made using the latest version of the Structured Clinical Interview for DSM-5 Disorders - Clinical Trials version (SCID5-CT) that assesses the current criteria for the diagnosis of PTSD. In DSM-IV, Criterion A required that the person be exposed to a traumatic event in which (1) the person experienced, witnessed, or was confronted with an event or events that involved actual or threatened death or serious injury, or a threat to the physical integrity of self or others, and (2) the person’s response involved intense fear, helplessness, or horror.

With DSM-5, the diagnostic criteria for PTSD underwent substantial revision, including criterion A. PTSD was moved out of the category of anxiety disorders and into a new chapter dedicated to Trauma- and Stressor-Related Disorders (one that now includes adjustment disorder). Criterion A was revised, three additional symptoms were added (increasing the number from 17 to 20), and the avoidance cluster was divided into avoidance and negative alterations in cognitions and mood. Criterion A now requires that the person be exposed to death, threatened death, actual or threatened serious injury, or actual or threatened sexual violence, as follows (one required): (1) direct exposure; (2) witnessing, in person; (3) indirectly, by learning that a close relative or close friend was exposed to trauma, where if the event involved actual or threatened death, it must be violent or accidental; or (4) repeated or extreme indirect exposure to aversive details of the events(s), usually in the course of professional duties (not including indirect non-professional exposure through electronic media, television, movies, or pictures).

In DSM-5, “subthreshold PTSD” is included in a section titled Other Specified Trauma/Stressor-Related Disorder (309.89), which includes adjustment disorders due to trauma/stress with a duration of more than 6 months without a prolonged duration stressor. As noted above, subthreshold disorders are more common than full PTSD and these symptoms are associated with substantial clinical impairment. In a recent WHO study of subthreshold PTSD, investigators recommended that subthreshold DSM-5 PTSD is most usefully defined as meeting two or three of DSM-5 criteria B-E (along with criterion A). These criteria will be used in the present study.

To limit the length of assessment, only the PTSD, mood disorders, anxiety disorders, and substance abuse disorders sections of the SCID-5 will be administered.

PTSD Symptom Severity. The severity of PTSD symptoms among members of the military has historically been assessed using the 17-item National Center for PTSD Checklist of the Department of Veterans Affairs (PCL). An alternative measure for documenting PTSD is the CAPS (Clinician Assessment of PTSD Symptoms), which can be administered by trained lay interviewers. The downside is that we also need a diagnostic measure for psychiatric co-morbidity, i.e., depressive disorder, anxiety disorder, substance abuse disorder, which CAPS does not assess. So, it may simply be easier to use a single diagnostic instrument, the SCID-5.

1 An alternative measure for documenting PTSD is the CAPS (Clinician Assessment of PTSD Symptoms), which can be administered by trained lay interviewers. The downside is that we also need a diagnostic measure for psychiatric co-morbidity, i.e., depressive disorder, anxiety disorder, substance abuse disorder, which CAPS does not assess. So, it may simply be easier to use a single diagnostic instrument, the SCID-5.
assesses the symptoms of PTSD as required for a diagnosis of PTSD in DSM-IV-TR. Participants are asked, “How much have you been bothered by each problem in the past month.” Possible response options are 1 (“not at all”), 2 (“a little bit”), 3 (“moderately”), 4 (“quite a bit”), and 5 (“extremely”). Responses are summed to create a PTSD severity scale that ranges from 17 to 85. A PCL cutoff of 50 or higher is usually used and considered a sensitive and specific indicator of PTSD. However, recent work suggests that a cutoff of 44 displays good specificity (96%) while maintaining acceptable sensitivity (72%) for PTSD in an active military population and decreasing the cutoff to 40 does not have a major impact on sensitivity and specificity.

The PCL-5 (based on DSM-5) is the latest revision of the PCL-S (stressor version) that is based on the new criteria. In the latest research, the 20-item PCL-5 has been found to have high agreement with the 17-item PCL-S (kappa=0.67), and both measures show identical reliabilities and nearly identical associations with combat exposure, major depression, generalized anxiety disorder, alcohol abuse, and functional impairment in soldiers. In that study, which involved 1707 active duty U.S. soldiers, a cutoff on the PCL-5 of ≥ 15 yielded a prevalence of 30% for PTSD. At a cutoff of ≥28, the prevalence was 16%. At a cutoff of ≥32, prevalence was 14%. And at a cutoff of ≥38, the prevalence was 10%. A cutoff of ≥ 38 is equivalent to cutoff of ≥50 on PCL-S (old criteria). As noted above, using a cutoff of 15 on the PCL-5, 30% met criteria for PTSD (24% of the sample met both DSM-IV-TR and DSM-5 criteria, 5% met only DSM-IV-TR and 5% met only DSM-5 criteria). At a cutoff of 32 on the PCL-5, 14% met criteria for PTSD (11% met both DSM-IV-TR and DSM-5 criteria, 3% met only DSM-IV-TR and 3% met only DSM-5 criteria). Among soldiers deployed to Afghanistan or Iraq, 24% scored 27 or higher on the PCL-5, which is equivalent to a PCL-S score of 40 or higher (kappa=0.73); 19% met both DSM-IV-TR and DSM-5 criteria, 5% met DSM-IV-TR only, and 5% met DSM-5 criteria only.

Given that we would like to include soldiers and veterans with subthreshold PTSD, we will use the PCL-5 cutoff of 27 or higher (equivalent to a PCL-S cutoff of 40 or higher) to identify soldiers and veterans for entry into the study. This means that if estimates of PTSD are similar to those found by Hoge and colleagues above, then 16% of all soldiers and 24% of all deployed soldiers would meet PCL-5 or DSM-5 criteria for PTSD. Unfortunately, comparable data for veterans is not yet available.

**Exposure to Trauma**

The Combat Experiences Scale (CES) will be administered at baseline to gauge soldiers’/veterans’ exposure to combat-related activities, such as taking fire, firing weapons, and perceived threat of injury or death. This 7-item measure is widely used to assess combat stressors. Each item is scored on a 5-point scale from 1 (never) to 5 (many times), with higher scores indicating greater exposure to combat-related stressors. The CES will be compared between treatment groups at baseline and if differences are found, will be controlled for in statistical analyses.

**Co-morbid Physical Illness**

**Physical and Cognitive Functioning.** Baseline physical functioning will be measured using the 10-item subscale from the SF-36 (possible score range 10-30, with higher scores indicating better functioning). Since a major aspect of the treatment in
the proposed study involves “cognitive therapy” and much of the data gathered is by self-report, measurement of cognitive function is vital. The Brief Mini-Mental State Exam (BMMSE)\textsuperscript{176} is an 18-item version of the standard 30-item cognitive screening instrument. Patients scoring 13 or lower on the BMMSE are considered significantly cognitively impaired (an exclusion criterion).

**Medical Co-Morbidity.** The Charlson Comorbidity Index identifies, classifies, and assigns comorbidity scores to 31 medical illnesses based on ICD-9 criteria.\textsuperscript{177} This measure will be supplemented by asking about the presence of other physical health conditions lasting or projected to last 3 months or longer including chronic pain, amputations, fractures, closed-head trauma (TBI), open cranial trauma, chest trauma, ocular injury, spinal cord injury, and muscle, nerve, vascular injuries caused by shrapnel or gunshot wounds, cardiovascular disorder, or any other physical health condition related to trauma resulting from serving in a combat or war theatre (including short-term and long-term health consequences). This expanded measure will also be used to determine whether a physical illness is co-mobid with PTSD (an inclusion criterion).

**Co-morbid Psychiatric Symptoms**

**Depression and Anxiety.** The SCID-5 will be used to diagnose depression and anxiety disorders at baseline. Because of its brevity, the Hospital Anxiety and Depression Scale (HADS) will be used to assess depression and anxiety symptoms on follow-up.\textsuperscript{178} This 14-item scale includes 7 items that assess anxiety and 7 items that assess depression. The scale is widely used in persons with physical health problems, and focuses more on cognitive symptoms rather than biological ones. Patients with somatic complaints can spuriously inflate scores on depression measures - despite not being depressed or anxious, per se. The psychometric properties of the scale indicate high internal reliability (Cronbach’s alpha 0.85 for anxiety subscale and 0.84 for depression subscale, overall 0.89), and reveal a 2-factor solution as predicted based on theoretical grounds.\textsuperscript{179}

**Substance Abuse.** Substance use and abuse will be assessed at baseline by the SCID-5, and symptoms will be tracked over time using the Alcohol, Smoking, and Substance Involvement Screening Test (ASSIST).\textsuperscript{180} The ASSIST is an 8-section questionnaire developed by an international group of substance abuse researchers for the World Health Organization. The ASSIST provides information about: (1) the substances people have ever used in their lifetime; (2) the substances they have used in the past three months; (3) urge to use substances; (4 and 5) problems related to substance use; (6 and 7) level of dependence; and (8) injecting drug use. There are 10 questions per sections 1-7 and 1 question per section 8 for a total of 10 to 71 questions, depending on responses. Substances addressed include: tobacco, alcohol, cannabis, cocaine, amphetamine type stimulants, sedatives, hallucinogens, inhalants, opioids, and other drugs. The ASSIST has been used in many studies to assess degree of substance use and its psychometric properties are well-established.\textsuperscript{181,182} Since we are primarily interested in current use, questions will be modified to assess use within the past 4 weeks.

Most CPT treatment protocols recommend that substance abuse is treated prior to implementing CPT; however, since this treatment protocol is translational in nature, and seeking to determine effects in “real world” situations (an effectiveness study), active substance abuse is not an exclusion criterion although will be carefully measured.
Sleep Quality
Sleep quality will be assessed at baseline and follow-up with the 19-item Pittsburgh Sleep Quality Index (PSQI). The PSQI is a self-rated measure of sleep quality and disturbances over the past month. Responses to items on the scale generate seven “component” scores: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication, and daytime dysfunction. The seven component scores are summed to yield a global score of sleep quality with a range from 0-21 (individual component scores range from 0-3). The Cronbach’s alpha is 0.83 and the test-retest reliability is r=0.85. A cutoff score of >5 has a 90% sensitivity and 87% specificity in distinguishing poor sleepers from good sleepers (kappa=0.75).

Guilt and Shame
Guilt and shame are known to be key factors that drive PTSD symptoms and may underlie moral injury. The 16-item Guilt and Shame proneness Scale (GASP) will be used to assess these personality characteristics. The GASP has four 4-item subscales: guilt negative behavior evaluation, guilt repair, shame negative self-evaluation, and shame withdraw. Items are rated on a 7-point Likert scale from very unlikely (1) to very likely (7), and have a total score for guilt and for shame of 7-56 each. Coefficient alphas range from 0.61 to 0.71 for the four subscales.

Moral Injury
The Moral Injury Questionnaire (MIQ) assesses the negative consequences associated with war-zone stressors that conflict with military veterans’ deeply held values and beliefs. This 20-item scale focuses on (1) acts of betrayal by peers, leadership, civilians or self; (2) acts of disproportionate violence inflicted on others; (3) incidents involving death or harm to civilians; (4) violence within military ranks; (5) inability to prevent death or suffering; and (6) ethical dilemmas or moral conflicts. Overall scale score is highly correlated with PTSD symptoms.

Negative Religious Coping
Religious and spiritual struggles often accompany PTSD, as discussed earlier. Religious or spiritual struggles will be measured using the 7-item negative religious coping subscale of the Brief RCOPE. Each item is assessed on a range from 0 (not at all) to 3 (a great deal) (with a total scale range from 0 to 21). This measure has been frequently associated with higher PTSD severity scores and will be a target of religiously-integrated CPT in the proposed study, along with guilt and shame, and moral injury.

Past Psychiatric History & Treatments
Personal & Family Psychiatric History. Prior psychiatric history, history of depression, and family psychiatric history will be gathered using an adapted version of the Duke Depression Evaluation Schedule. First, participants will be asked if they ever in the past experienced an episode of two weeks or longer of depression or loss of interest (yes vs. no). Second, patients will be asked if they have ever experienced a mental or
nervous condition that required some form of treatment (yes vs. no). Third, family psychiatric history will be assessed by asking if any first degree relative (parents, siblings, children, grandchildren) ever had a mental or nervous condition, ever saw a psychiatrist or therapist, was ever admitted to a psychiatric hospital, ever took nerve medicine for three months or more, made a suicide attempt or committed suicide, or had a problem with drugs or alcohol (yes vs. no).

**Current and past treatments for psychiatric disorder.** Current and past treatments for psychiatric disorders will be examined. The participant will be asked if he or she (1) currently takes medication for any emotional or mental health condition (antidepressant, anti-anxiety, anti-psychotic, other), (2) has ever taken any medication of this nature in the past (antidepressant, anti-anxiety, anti-psychotic, other), (3) is currently receiving counseling or psychotherapy (type of therapy and when last treatment session was received), and (4) ever received counseling or psychotherapy in the past (and how long ago).

**Religiosity/Spirituality**

Besides denomination, single items assessing self-rated religiosity (1- not at all religious, 2- somewhat religious, 3- moderately religious, 4- very religious), self-rated spirituality (1- not at all spiritual, 2- somewhat spiritual, 3- moderately spiritual, 4- very spiritual), private religious practices, and religious attendance will be administered, along with multi-item measures of daily spiritual experiences (16 items), intrinsic religiosity (10 items), and religious commitment (10 items). Each of these measures have established psychometric properties including solid reliability and validity indicators. Single items and multi-item scales will be combined to form a 40-item global religiosity/spirituality measure that will be used in statistical analyses.

**Positive Emotions**

The benefits of addressing religious beliefs in therapy may stem partly from redirecting attention from a focus on trauma, loss and preoccupation with self to cognitions that focus on hope, purpose and meaning in life, optimism, and post-traumatic growth, which have been shown to predict better mental health and fewer clinical symptoms. Validated scales will be used to assess each of these positive emotions both at baseline and during follow-up evaluations to assess change over time in response to treatment and their relationship with PTSD symptom severity.

**Hope.** The 6-item State Hope Scale (SHS) will be used to assess this construct. The SHS has a two-factor structure (agency and pathway) with each factor consisting of three items; and the factor structure has been confirmed in a separate study. The internal consistency of the SHS is high (alpha=0.93), as well as the test-retest reliability (range 0.48-0.93). Hope has been shown to mediate the effects of CPT on PTSD.

**Purpose in Life.** The 20-item Purpose in Life (PIL) Scale assesses PIL based on theories about positive psychological health and lifespan development. Each item is rated on a 7-point scale and the total PIL score ranges from 20 to 140. High scores on the PIL scale indicate that participants have goals and a sense of direction in life, feel that there is meaning to their lives both currently and in the past, hold beliefs that give life purpose, and have aims and objectives for living; low scores reflect lack of meaning or direction in life, few goals, and inability to see purpose in past events. The reliability
and validity of the PIL scale has been established in numerous studies. The measure has been shown to have good split-half and test-retest reliability. The PIL scale had a Cronbach’s alpha of 0.91 in the original study, and there is evidence for both convergent and discriminant validity.

Optimism. The Life Orientation Test-Revised (LOT-R) is a 10-item measure of dispositional optimism developed in 1985 by Scheier and Carver and revised in 1994. This measure is the most common instrument used to assess optimism, and has been administered extensively in psychological research over the past 30 years. The LOT-R predicts medical outcomes in persons with physical illness, independent of depression and personality traits. The 10 items are scored on a scale from strongly disagree (0) to strongly agree (4) (overall range 0-40).

Self-esteem. Self-esteem is being measured using the 10-item Rosenberg Self-Esteem Scale (SES), which is the standard measure in the field. The SES measures global self-worth by assessing both positive and negative feelings about the self. All items are answered on a 4-point scale from strongly agree (1) to strongly disagree (4). Score range is 10-40. In the validation study involving a community sample of 503 adults, reliability (Cronbach’s alpha) was 0.91.

Post-Traumatic Growth. PTG will be assessed using the 10-item PTGI-SF scale, which assesses positive psychological changes as a result of struggling with life stressors. After designating their “worst” stressful event respondents are asked to rate items such as “I changed my priorities about what is important in life” on a scale from 0 (did not experience) to 5 (a very great degree). Scores range from 0 to 50 and higher scores indicate the degree of positive psychological change as a result of the negative life event. Internal consistency of overall scale is high (α= 0.95), and consists of five subscales that also have high reliability alphas: development of more intimate relationships (α= 0.84), recognition of new possibilities or paths for one’s life (α=0.85), greater sense of personal strength (α= 0.89), greater spiritual development (α=0.92), greater appreciation of life (α=0.80).

Social Support

Perceptions of social support and degree of social engagement are known to be affected by PTSD and influence recovery from PTSD. Social support will be measured with the social interaction and subjective support subscales of the Duke Social Support Index. This 11-item brief version of the DSSI asks about time spent interacting with friends, neighbors, and family, both in person and on the telephone, and also assesses the subject’s satisfaction with social interactions and support received. The brief DSSI has been validated in adults with chronic health problems, and has a score range of 11 to 33.

Assessments and Procedures

Screening, baseline assessment and follow-up assessments are described below.

Screening Assessment. The screening evaluation, which will usually take place by telephone, will include an initial explanation of the study and determination of whether initial eligibility criteria are met (15 min).

- Is an active duty soldier or veteran
- Has or had a diagnosis or symptoms of PTSD
- Has comorbid physical illness or injury
- Has sleep problems
- Religion at least somewhat important
- English-speaking
- Willing to participate in a psychotherapy study involving 12 treatment sessions twice weekly over 6 weeks and completing assessments at 3, 6, 12 and 24 months
- No severe cognitive impairment
- No Cognitive Processing Therapy within past 4 weeks

If initial telephone screen is passed, participants will be scheduled for an in-person screening evaluation. At that time, the study will be more fully explained and written consent to participate will be obtained. The screening process will be completed at this time. The in-person screening evaluation will consist of the following (30-45 min):

- Review responses to initial telephone screen to ensure initial eligibility
- Brief Mini-Mental State Exam (12 items)
- PCL-5 (20 items)
- SCID-5 (PTSD, mood disorders, anxiety disorders, substance abuse sections only)
- Self-rated religiosity and spirituality (2 items)
- Charlson Comorbidity Scale (31 items)

**Baseline Evaluation.** If participant is eligible, study personnel will explain the study again to the participant and what is expected, and will then perform the baseline evaluation (45-60 min):

- Demographics (12 items)
- Combat Experiences Scale (7 items)
- Physical functioning from SF-36 (10 items)
- Hospital Anxiety and Depression Scale (14 items)
- ASSIST (10 to 71 items, depending on response)
- Pittsburgh Sleep Quality Index (19 items)
- GASP (guilt and shame) (16 items)
- Moral Injury Questionnaire (20 items)
- Negative religious coping (7 items)
- Personal/family psychiatric history (3 items)
- Current/past treatments for psychiatric disorder (10 items)
- Religiosity/spirituality (40 items)
- State Hope Scale (6 items)
- Purpose in Life Test (20 items)
- Life Orientation Test (optimism) (10 items)
- Self-esteem (10 items)
- Post-traumatic Growth (10 items)
- Brief Duke Social Support Index (11 items)
Follow-up Evaluations. Participants will be reassessed by research coordinators (blind to treatment group) at 3 weeks, 6 weeks, 12 weeks, and 24 weeks after the baseline evaluation either in-person or by telephone (60 min):

- PCL-5 (20 items)
- Hospital Depression and Anxiety Scale (14 items)
- ASSIST (10 to 71 items, depending on response)
- Pittsburgh Sleep Quality Index (19 items)
- Current treatments (only at 6 weeks and 24 weeks) (2 items)
- Physical functioning from SF-36 (10 items)
- Religious commitment (10 items)
- Moral Injury Questionnaire (20 items)
- Negative religious coping scale (7 items)
- State Hope Scale (6 items)
- Purpose in Life Test (20 items)
- Life Orientation Test (10 items)
- Brief Duke Social Support Index (11 items)
- Post-traumatic Growth (10 items)
- GASP (guilt and shame) (16 items)
- Self-esteem (10 items)

Response Burden and Subject Payments

We anticipate that the initial interview may last as long as 90 minutes and follow-up interviews as long as 60 minutes. In order to minimize response burden, we have limited the number of measures and use abbreviated measures of constructs whenever possible. Our research coordinators will have to be carefully selected so that they can keep the participant’s attention and manage the participant’s frustration level during the assessments.

We will pay participants $25 for in-person screening/baseline evaluation and $25 per follow-up assessment after they complete the study ($125 total). Active military personnel can only be paid if the activity takes place outside of normal work hours (7:30A-4:30P on weekdays); veterans can be paid regardless of when the interview is done.

Statistical Analyses

Both primary and secondary endpoints will be analyzed using the intention-to-treat (ITT) principle, except for per-protocol analyses (see below). Power analyses indicate that a sample size of 300 participants will be adequate to identify a significant difference between treatment groups in order to test our primary hypothesis (1.1). Anticipating a 25% dropout rate, a final sample of 226 soldiers/veterans, 113 in each intervention arm, will produce a greater than 80% power to detect a small to moderate difference between groups (Cohen’s d=0.38) at a p value of 0.05 (2-tailed test) for the primary outcome (PTSD symptom severity on the PCL-5) assessed at 6-weeks from baseline at the end of treatment. For descriptive purposes only, we will compare PCL-5 scores between treatment groups at baseline, 3 weeks, 6 weeks, 12 weeks, and 24 weeks.
to determine visually whether there are any differences in effects of RCPT vs. CPT on PTSD symptom severity.

Primary Analysis: To test Hypothesis #1.1, we will use growth curve analyses using random intercept and slope to examine trajectories of change in PCL-5 scores between the two treatment arms through 6 weeks (taking into account PCL-5 scores at 0, 3, and 6 weeks) (Model 1).¹ This will allow participants with data for at least one time point to be included in the analysis and help to address the problem of missing data. The model will include the fixed effects of treatment group, time, time squared (if significant), and the interaction of treatment group with time. Military type (active duty soldiers vs. veterans), PTSD type (subthreshold vs. standard PTSD), and psychiatric co-morbidity (present vs. absent) will be examined in these models to determine their effects on treatment outcome (if there are baseline differences not addressed by randomization).

Secondary Analyses: To test Hypothesis #1.2 (persistence of effects), we will compare the effects of RCPT vs. CPT through 24 weeks by including PCL-5 severity score at 24 weeks in Model 1 (Model 2). To test Hypothesis #2, we will develop growth curve models comparable to Models 1 and 2 with depressive symptoms, anxiety symptoms, substance use, and sleep quality as primary outcomes. To test Hypothesis #3, we will include hope, purpose in life, optimism, post-traumatic growth, self-esteem, social support, guilt/shame, and negative religious coping scores one at a time and then all together in growth curve Models 1 and 2 to determine if these factors explain the benefit of RCPT over CPT on PTSD severity and co-morbid mental and sleep problems (if there is a benefit). Hypothesis #4 will be tested by developing growth curve models comparable to Models 1 and 2 with moral injury as the outcome, rather than PTSD symptoms, mental, or sleep quality. To test Hypothesis #5 (moderating effects of religiosity, where moderation refers to a change in slope in one group but not the other), we will examine the interaction between treatment group and overall religiosity. This will be done by entering the summed measure of religiosity into the growth curve models (Model 1 and Model 2) along with the interaction between religiosity and treatment group. If the interaction is significant, then we will examine the effect of RCPT vs. CPT on PTSD severity in those with high vs. low religiosity. The summed religiosity variable will be dichotomized into those scoring one-half standard deviation above the mean or higher (high religiosity) vs. others (low religiosity), and models run in each category. Secondary analyses will include repeating the above analyses per-protocol, i.e., including only participants who have completed at least 6 of the 12 treatment sessions.

Effect sizes (Cohen’s d) will be determined using t-statistic values and degrees of freedom from growth curve models. All statistical analyses will be done using SAS (version 9.3; SAS Institute Inc., Cary, North Carolina). The significance level will be set at p=0.05 for testing the primary hypothesis above (1.1) and at p=0.01 for secondary analyses, a more conservative value given the multiple statistical tests performed (but short of the too conservative Bonferroni correction for these exploratory analyses).

¹ We considered using repeated measures ANOVA or ANCOVA, with between and within subject comparisons and if significant, post-hoc t-tests, although this would require adjusting the analysis of the primary hypothesis for multiple tests. This was a primary reason for deciding on a single growth curve model.
HUMAN SUBJECTS CONSIDERATIONS

We will obtain full IRB approval for the study from Eisenhower Army Medical Center (EAMC) as the primary site, which will be handled by Scott Mooney, the site PI there. We will then seek a Memorandum of Understanding for Womack Army Medical Center (WAMC), with WAMC recognizing EAMC as parent IRB of record and WAMC as a sister site. Afterwards, WAMC will complete an abbreviated site-specific addendum showing how the parent protocol will be carried out there. WAMC will complete an abbreviated site-specific addendum showing how the parent protocol will be carried out there. Full IRB approval is likely to be necessary at the VAMC in Augusta and Duke as well.

This human subjects’ research meets the definition of ‘Clinical Research’. The risks associated with this study are the risks involved the loss of confidentiality and the possible worsening PTSD with adverse psychological consequences that may follow. All records will be kept confidential to the extent permitted by law. Patient identifying information will not be transmitted to or databased in RedCap (i.e., it will be de-identified). Access to such information will be allowed only to certain authorized members of the research team, institutional staff, and regulatory agencies. In reporting the results, privacy will be protected by using a coding system that does not reveal the identity of individuals, and by reporting group results.

Recruitment and Consent Procedures

The recruitment procedures for our study will include a thorough explanation of the study, time commitment, possible risks and benefits, and alternatives for treatment. Participants will be informed about the purposes of the research study. Specifically, they will be informed about the diagnosis of PTSD and its treatment. Through a combination of written materials and the consent form, they will be told that this is a treatment study, and each of the two study arms will be described. They will be informed that there is an equal chance (random assignment) to be assigned to one or the other of the two study arms. Details of the study will be explained, as well as the differences between early termination and dropping out and the consequences of each. They will be further informed that their identity will be kept confidential through the use of a confidential code number that will allow all information to be entered into the database in an anonymous fashion, such that information cannot be linked or traced to any person outside of the immediate investigative team. Aside from treatment planning, all information will be used only for group statistical analyses. All study participants will be told the expected duration of the study and informed that subjects' consent can be withdrawn at any time, at no risk to having other treatment in their clinical setting withheld. Alternatives to participation will also be noted in the consent form.

Risks to Subjects

This investigation will be conducted with prior approval from DUMC, EAMC, CN-VAMC, and WAMC Institutional Review Boards (IRBs). Details of how potential subjects will be ascertained and recruited for study participation, and how their rights and welfare will be protected, will be provided to these IRB’s.

Risk to Confidentiality. Personal identifying information, such as name, address, driver’s permit, Social Security Number, etc., will not be entered into the database.
However, other identifying data fields, including date of birth, treatment group, and questionnaire data will be recorded on the case report forms and entered directly into RedCap, the secure database used for all Duke University studies. The control of access to the database will be managed centrally by the CTCC through user passwords linked to appropriate access privileges. This protects forms from unauthorized view and modification and from inadvertent loss or damage. Database servers are secured by a firewall as well as through controlled physical access.

**Miscellaneous Risks.** If at any time a study interviewer or study therapist believes that there is a significant risk of harm with a subject who is participating in the study (i.e., getting upset, expressing suicidal thoughts, etc.), he or she will consult with the study site PI (a psychologist or psychiatrist). This person will then assess the patient. If they believe there is a significant risk, then they will immediately do whatever is necessary to ensure the safety of the subject.

**Potential Benefits to Participants and Others**

The benefits to participants in this study are that they will receive free psychotherapy for their PTSD from licensed therapists trained in CPT and supervised by Duke faculty experienced in delivering CPT. The benefits to others will result from our learning whether integrating patients’ religious beliefs/practices into CPT will result in faster and more complete remission of PTSD than that achieved with conventional CPT that does not typically utilize patients’ religious resources in therapy.

**Premature Withdrawal, End-of-Study Debriefing, and Referral Options**

All prematurely terminating subjects will be asked to complete the full assessment batteries. Some patients may exhibit transient worsening at an assessment point, but in the judgment of the therapist and supervisor (and study psychologist, as necessary) warrant continuation in the study. Should severe worsening occur, then subjects will be withdrawn from the study. There are no procedures for maintenance of treatment following premature withdrawal from the study or at the end of the 12 treatment sessions. Hence, ethical principles require that at study withdrawal or end of the treatment period, all participants be given recommendations for any indicated further treatment and appropriate referrals. To standardize this process across therapists, we will use a standardized debriefing script. Briefly, this script will a) provide the subject a chance to state any concerns or questions they have; b) provide a summary of progress using clinical indicators; c) outline the possible available treatments; and d) make recommendations about appropriate continuing treatment. All subjects needing or requesting further treatment will be given a list of possible providers for the recommended treatment and will be told that a clinical report could be sent with the subject’s authorization to any new treatment provider(s).

**Subject Safety and Adverse Events Reporting**

An adverse event (AE) is any untoward, undesired, or unplanned event in the form of signs, symptoms, disease, or laboratory or physiologic observations occurring in a person in a research study. The event does not need to be causally related to the research study. Site PIs will record all AEs and serious adverse events (SAE) on source documents and data forms, as well as complete appropriate adverse event reporting forms.
and forward to the Clinical Trials Control Center (CTCC) within the required time frame for reporting, but in no case beyond these time frames. SAEs will be reported to the CTCC within 24 hours of occurrence via fax or e-mail with a written report submitted within seven (7) calendar days. The site PIs will follow up on all AEs and SAEs until the events have subsided or until the condition has stabilized. The CTCC will maintain detailed records of all AEs and SAEs reported by the site PI’s in accordance with good clinical practice and applicable regulations (with oversight by Dr. Koenig).

**Regular Teleconferences**

Uncertainties regarding how to administer the protocols are certain to arise. Members of the Steering Committee will engage in monthly teleconferences. Using the teleconference mechanism, a set of precedents will be established regarding how best to manage situations that call for screening and enrollment of subjects, and flexible administration of the CPT protocols. In turn, this set of precedents will contribute to the development of a common culture, which will insure that screening procedures and assessments are administered in the same fashion by therapists, and CPT supervisor/s are training and supervising therapists in a similar fashion.

**Timeline**

Considering a startup and training period of 3 months, a recruitment phase of 24-30 months, and 3-9 months to clean the data and write the papers at the end of the trial, we anticipate a 3-year project (ideally, January 1, 2016-December 31, 2018).

**Budget and Budget Justification**

*Personnel: Duke University Medical Center*

**Harold G. Koenig, M.D.** Dr. Koenig will serve as the Lead/Coordinating Principal Investigator (Lead PI), will draft the protocol(s), identify team members, assist with the hiring of interviewers, assist with the training of interviewers and therapists, preside over steering committee meetings, monitor recruitment at each of the three sites, ensure that study goals are met, assist with statistical analyses, and provide first drafts of papers coming from this project. These responsibilities will require 35% effort (FTE) over the 3 years of the project; of this, he will match 10% and request 25% per year from the grant: $118,278 x 25% x 3 = $88,789.

**Keisha-Gaye N. O’Garo, Psy.D., ABPP** Dr. O’Garo (co-investigator) is a skilled practitioner of Cognitive Processing Therapy (CPT), is on the faculty at DUMC in psychology, and has worked for years treating soldiers with PTSD at Womack Army Medical Center (WAMC), Fort Bragg. She will assist Dr. Pearce in developing religiously-integrated CPT, including the treatment manuals for the 5 religious faiths and the treatment workbooks for therapists and patients. She will also lead the training of the 6 therapists for the study and serve as supervisor during the trial, along with Dr. Pearce. She will serve as the primary monitor of recruitment at the WAMC site, will form the research team there, including identification of a local/site PI, site coordinator (recruiter/interviewer), and therapists. She will also serve on the steering committee and assist in the writing of the papers from the study. These duties will take 30% effort (FTE) over the 3 years of the project, which we are requesting: $150,000 x 30% x 3 = $135,000.
Michelle Pearce, Ph.D. Dr. Pearce (co-investigator) is a skilled practitioner of Cognitive Behavioral Therapy (CBT), developed the religiously-integrated CBT intervention used in our recent clinical trial, and trained and supervised the therapists who delivered it. She has extensive experience in cognitive therapies. Previously on the faculty at Duke in medical psychology, she is now an adjunct professor at Duke and professor at the University of Maryland School of Medicine. She will work with Dr. O’Garo to develop the religiously-integrated CPT, and train, supervise, and help identify the study therapists. She will also serve on the steering committee and assist in the writing of the papers from the study. These duties will take 20% effort (FTE) over 3 years of the project, which we are requesting: $150,000 x 20% x 3 = $90,000.

Clinical Trials Coordinator (TBD). This person (master’s degree of higher) will be in charge of the Clinical Trials Control Center (CTCC), and be responsible for randomizing subjects to treatment groups and therapists, connecting subjects to their therapists, working with each of the three research coordinators to schedule and track baseline and follow-up assessments, working with each of the six therapists to schedule and track therapy visits, and dealing with any database (Redcap) issues related to acquiring data from the site research coordinators. This person will also arrange to have 150 therapist sessions randomly identified and those sessions recorded and transcribed, and then entered into the Redcap system. This person will need extensive experience as a clinical trials coordinator. These responsibilities will take 50% effort FTE, and we are requesting: $80,000 x 50% x 3 = $120,000.

Interfaith Panel. The interfaith panel consists of mental health professionals (at MD or PhD level) who are experts on integrating religion into psychotherapy from Jewish, Hindu, Buddhist, and Muslim perspectives. They will assist in the development of the non-Christian CPT manuals and workbooks, and in the supervision of therapists who provide treatment to subjects from those traditions when enrolled in the study. We are requesting $3,000 for each member of the panel, or $12,000 total.

Business Office (Judi Miller). This individual will be in charge of preparing the paperwork for the grant submission, developing contracts with the funding agencies, developing subcontracts with the three recruitment sites, arranging payment of all personnel outside of Duke, and monitoring the budget and expenses. These duties will take 25% effort (FTE) over 3 years of the project, which we are requesting: $60,000 x 25% x 3 = $45,000.

Statistician (TBD). Will oversee data management and will perform with Dr. Koenig all of the statistical analyses for this project and participate in the papers that result. These duties will take 10% effort (FTE) over 3 years of the project, which we are requesting: $150,000 x 10% x 3 = $45,000.

Data Management (TBD). Will be in charge of data management, including all information collected at the three sites. This includes monitoring data collection throughout the trial to ensure that data is complete, and after the trial is completed, preparing the data for statistical analyses. These duties will take 10% effort (FTE) over 3 years of the project, which we are requesting: $75,000 x 10% x 3 = $22,500.

Therapist Payments. Therapists will be paid $75 per 50-min session, and $1000 each for time involved in initial training and supervision throughout the trial. If 300 participants complete all 12 sessions, then therapist will need to deliver 3,600 therapy sessions during the trial. The total cost for the therapy is estimated to be $75 x 3,600 or
The cost of time for training and supervision will be $1000 x 6=$6,000. Total amount requested=$276,000.

**Subject Payments.** Participants will receive $25 for the screening/baseline evaluation whether or not they qualify, and then $25 for each of the 4 follow-up assessments (total $125). If 300 subjects participate in the trial, the cost will be 300 x $125=$37,500; assuming 25% x 300 do not qualify during in-person screening (n=75), this adds $1,875, for a total cost of $39,375, which is what we are requesting.

**Transcript Rater.** To read through and rate a transcribed 50-min therapy session should take 1 hour each. Given that the rater (PhD level) will have to do this for 150 transcripts, this should take 150 hours at $100/hour =$15,000, which we are requesting.

**Henry Jackson Foundation Administrative Costs.** Since grants (or subcontracts) cannot be accepted by military or VA institutions, the HJF will be engaged to hire contractors (Research Coordinators and Data Technicians) to work at EAMC, WAMC, and the Augusta VAMC. For hiring and managing these personnel, we estimate a charge of $135,000 (15% of salary and fringe for hired personnel).

**Non-Personnel Costs**

**Supplies.** Supplies include paper, Xeroxing, computer supplies, conference call charges, open access journal fees, and so forth. $1500 per year for the Duke site (which will be paying for conference calls for monthly steering committee meetings and for 1-4 times/mo supervision of therapists by their supervisors at all three recruitment sites) is requested ($4,500 total).

**Licensing costs.** Wherever possible, from a cost containment standpoint, public domain/free access tools were selected as outcome measures in the study. However, all measures were the best available from a scientific standpoint, and some of these tools do have a site license fee, including the SCID-5-RV, PCL-5, and several of the other measures. The licensing fee for the SCID-5-RV from American Psychiatric Publishing is $3,860. Other scales to be used in the study also have licensing fees and we anticipate that $5,000 will cover the SCID-5-RV and others.

**Recording and transcription costs.** To assess therapist adherence to the manual will require the recording of 150 sessions lasting 50-min each, which will then need to be transcribed. Each of the 6 therapists will need a quality tape recorder and disks and batteries for the recorder. We estimate the costs of these recorders and supplies will be $200 each x 6 therapists=$1,200. Assuming each session takes 2 hours to transcribe x 150 at $35/hour=$10,500. The total cost requested, then, is $11,700.

**RedCap Database.** RedCap is the protected database that all information from assessments will be entered into (via Internet), stored, and transformed into a SAS or SPSS dataset for analysis. For programming the questionnaires into RedCap, the cost is estimated to be $3,000.

**Travel (O’Garo and Koenig).** Dr. O’Garo will be traveling by car from Durham to the WAMC in Fayetteville, NC (180 mile roundtrip), on a twice monthly basis to monitor, train, and supervise therapists at that site, and will be flying to conduct the training and re-training at the other two sites. Twice monthly car expenses x 30 months x 180 x 0.60/mi (projected 2016 IRS rate)=$6,480. Travel expenses for onsite visits each year to the EAMC and CN-VAMC site (both in Augusta, GA) for both Dr. O’Garo and Dr. Koenig will incur the following costs: flight ($400) plus 1 night hotel ($100) and 2
day food expenses ($100)=$600 x 2 people x 3 years = $3,600. Total requested: $10,080.

Eisenhower Army Medical Center

Scott Mooney, Ph.D., ABPP-CN, DAC. Dr. Mooney (co-investigator) is Researcher & Lead Neuropsychologist in Dept. of Orthopedics, Neurosciences, & Rehabilitation at EAMC. He will serve as site PI at EAMC. His responsibilities will include helping to draft the IRB proposal, hire and supervise the EAMC research coordinator (interviewer/recruiter) and data technician, identify and participate in the training of therapists for that site, and monitoring recruitment and therapist activities. He will serve on the steering committee, and will assist with the drafting of papers that result from the study. He will also be responsible for dealing with any administrative hurdles at the EAMC site, including preparing the EAMC IRB proposal and WAMC site-specific addendums (with Dr. Koenig’s assistance) and ensuring cooperation by personnel in the PTSD outpatient and inpatient settings at EAMC and Fort Gordon where recruitment will take place. He will also make efforts to ensure the safety of any subjects whose emotional state deteriorates during screening or while in the study. These duties will take 20% effort (FTE) over 3 years of the project, which will be provided as matching funds ($180,000 x 20% x 3 = $108,000).

Research Coordinator (TBD). This individual (master’s degree level) will be in charge of recruitment (screening, explaining study and administering consent), in-person baseline and all follow-up assessments, as well as working with the Data Technician (see below) to ensure that the data collected are accurately entered into the RedCap database. This person will also be responsible for advertising the study, contacting potential participants, and ensuring that recruitment stays on schedule, enrolling a minimum of 1-2 participants per week throughout the 24-month recruitment period. Given the effort necessary to identify and recruit subjects at this site, and conduct follow-up assessments at 3, 6, 12, and 24 weeks, this will require 100% effort (FTE) over 3 years, including training and a buffer time towards the end of the study to ensure that recruitment goals are met. Thus, we are requesting $75,000 x 100% x 3 = $225,000.

Data Technician (TBD). A data technician (DT) will be needed to (a) enter all data collected into the RedCap database, and re-enter a second time for double-checking to ensure that no data entry errors were made during the first entry; (b) help the Research Coordinator to identify potential subjects through advertising, reviewing medical records or other lists under the direction of the local/site PI; (c) work with the CTCC to schedule follow-up assessments and therapist treatment sessions; (d) assist preparation of forms for IRB submission and renewal; (e) assist the site PI with any paperwork regarding the study and related secretarial duties; and (f) assist participants and therapists in whatever needs they may have during the course of the study. These responsibilities will require 50% effort (FTE) over 3 years. Thus, we are requesting $50,000 x 50% x 3 = $75,000.

Miscellaneous costs. The IRB at EAMC charges a one-time fee of $3,000. To set up an office with computer and phone setup is $2,500 and $1000/year for maintenance of computer/phone/supplies for the project coordinator ($5,500) and $1,250 and $500/year for maintenance of computer/phone/supplies for the data technician ($2,750). This comes out to a total cost of $3,000 + $5,500 + $2,750 =$11,250 over 3 years, which we are requesting.
Nagy Youssef, M.D. Dr. Youssef (co-investigator) is Medical Director, Acute Inpatient Psychiatric Services at Charlie Norwood VA Medical Center in Augusta GA (CN-VAMC), and is Clinical Assistant Professor Department of Psychiatry and Health Behavior at the Medical College of Georgia at Georgia Regents University. He is a physician scientist and will serve as site Co-PI at CN-VAMC. His responsibilities will include helping to draft the proposal, hire and supervise the CN-VAMC research coordinator (interviewer/recruiter) and data technician, identify and participate in the training of therapists for that site, and monitoring recruitment and therapist activities. He will serve on the steering committee, and will assist with the drafting of papers that result from the study. He will also be responsible for dealing with any administrative hurdles at the CN-VAMC site, including preparing the CN-VAMC IRB proposal (with Dr. Koenig’s assistance) and ensuring cooperation by personnel in the PTSD outpatient and inpatient settings at CN-VAMC where recruitment will take place. He will also make efforts to ensure the safety of any subjects whose emotional state deteriorates during screening or while in the study. These duties will take 20% effort (FTE) over 3 years of the project, which will be $185,000 x 20% x 3 = $111,000 [salary will be divided with other site Co-PI].

Research Coordinator (TBD). This individual (master’s degree level) will be in charge of recruitment (screening, explaining study and administering consent), in-person baseline and all follow-up assessments, as well as working with the Data Technician (see below) to ensure that the data collected are accurately entered into the RedCap database. This person will also be responsible for advertising the study, contacting potential participants, and ensuring that recruitment stays on schedule, enrolling a minimum of 1-2 participants per week throughout the 24-month recruitment period. Given the effort necessary to identify and recruit subjects at this site, and conduct follow-up assessments at 3, 6, 12, and 24 weeks, this will require 100% effort (FTE) over 3 years, including training and a buffer time towards the end of the study to ensure that recruitment goals are met. Thus, we are requesting $75,000 x 100% x 3 = $225,000.

Data Technician (TBD). A data technician (DT) will be needed to (a) enter all data collected into the RedCap database, and re-enter a second time for double-checking to ensure that no data entry errors were made during the first entry; (b) help the Research Coordinator to identify potential subjects through advertising, reviewing medical records or other lists under the direction of the local/site PI; (c) work with the CTCC to schedule follow-up assessments and therapist treatment sessions; (d) assist preparation of forms for IRB submission and renewal; (e) assist the site PI with any paperwork regarding the study and related secretarial duties; and (f) assist participants and therapists in whatever needs they may have during the course of the study. These responsibilities will require 50% effort (FTE) over 3 years. Thus, we are requesting $50,000 x 50% x 3 = $75,000.

Miscellaneous costs. The IRB at the Augusta VA charges a one-time fee of $3,000. For the project coordinator, to set up an office with computer and phone setup is $2,500 and $1000/year for maintenance of computer/phone/supplies ($5,500). For the half-time data technician, these costs will be $1,250 and $500/year for maintenance of computer/phone/supplies ($2,750). We are also requesting miscellaneous supplies
Womack Army Medical Center

Jay E. Earles, PsyD, ABPP. Dr. Earles is Chief of Behavioral Health at WAMC. His responsibilities will include helping to draft the proposal, hiring and supervising the WAMC research coordinator (interviewer/recruiter) and data technician, identifying and participating in the training of therapists for that site, and monitoring recruitment and therapist activities. He will serve on the steering committee, and will assist with the drafting of papers that result from the study. He will also be responsible for dealing with any administrative hurdles at the WAMC site, including preparing the IRB proposal (with Dr. Koenig’s assistance) and ensuring cooperation by personnel in the PTSD outpatient and inpatient settings at WAMC and Fort Bragg where recruitment will take place. He will also make efforts to ensure the safety of any subjects whose emotional state deteriorates during screening or while in the study. These duties will take 20% effort (FTE) over 3 years of the project, which will be provided as matching funds ($180,000 x 20% x 3 = $108,000).

Research Coordinator (TBD). This individual (master’s degree level) will be in charge of recruitment (screening, explaining study and administering consent), in-person baseline and all follow-up assessments, as well as working with the Data Technician (see below) to ensure that the data collected are accurately entered into the RedCap database. This person will also be responsible for advertising the study, contacting potential participants, and ensuring that recruitment stays on schedule, enrolling a minimum of 1-2 participants per week throughout the 24-month recruitment period. Given the effort necessary to identify and recruit subjects at this site, and conduct follow-up assessments at 3, 6, 12, and 24 weeks, this will require 100% effort (FTE) over 3 years, including training and a buffer time towards the end of the study to ensure that recruitment goals are met. Thus, we are requesting $75,000 x 100% x 3 = $225,000.

Data Technician (TBD). A data technician (DT) will be needed to (a) enter all data collected into the RedCap database, and re-enter a second time for double-checking to ensure that no data entry errors were made during the first entry; (b) help the Research Coordinator to identify potential subjects through advertising, reviewing medical records or other lists under the direction of the local/site PI; (c) work with the CTCC to schedule follow-up assessments and therapist treatment sessions; (d) assist preparation of forms for IRB submission and renewal; (e) assist the site PI with any paperwork regarding the study and related secretarial duties; and (f) assist participants and therapists in whatever needs they may have during the course of the study. These responsibilities will require 50% effort (FTE) over 3 years. Thus, we are requesting $50,000 x 50% x 3 = $75,000.

Miscellaneous costs. The IRB at WAMC charges a one-time fee of $3,000. For the project coordinator, to set up an office with computer and phone setup is $2,500 and $1000/year for maintenance of computer/phone/supplies ($5,500). For the half-time data technician, these costs will be $1,250 and $500/year for maintenance of computer/phone/supplies ($2,750). We are also requesting miscellaneous supplies (paper, Xeroxing, etc.) at $500/year. This comes out to a total cost of $3,000 + $5,500 + $2,750 + $1500 = $12,750 total over 3 years, which we are requesting.
**Budget Requested:**

Direct Costs: 2,125,730 (+ 252,000 salary matching)
Indirect costs (15% Duke): 318,860
Total 2,444,590 for individual donations
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